Remarks

Claims 17, 19-23 and 25-37 are pending in this application. Claims 17, 23 and 35 have been amended in various particulars as indicated hereinabove.

Claims 35-37 were rejected under 35 U.S.C. 112, second paragraph. Applicant believes that Claims 35-37 as amended are now in compliance with the requirements of 35 U.S.C. 112, second paragraph.

Claims 17, 19-23, 25-28 and 35-37 were rejected under 35 U.S.C. 102(b) or, in the alternative, under 35 U.S.C. 103(a) over Jonsson *et al.* (US Patent No. 4,292,324). This rejection is respectfully traversed for the following reasons.

Applicant amended independent Claims 17, 23 and 35 to emphasize the important aspect of the invention, which, as follows from pages 5-6 of the Office Action, has not been appreciated by the Patent Office.

In particular, on page 5 of the Office Action the Patent Office wrote that "in accordance with applicant's explanation, the only difference between the pharmaceutically active compound and a potentiated form of said compound is in concentration of said compounds." Further on page 6 the Patent Office wrote that "[F]urther, it is not clear how the combination of compositions comprising the same compound at different concentrations is different from a composition comprising said compound." Applicant disagrees with such interpretation of the invention and explains as follows.

Applicant refers now to amended independent Claim 17, in which it is specifically claimed that it is only the initial substance that is the same, and that an active medicinal substance and a potentiated medicinal preparation are made from that same initial substance (see page 7 of the specification, stating that "...[t]he potentiated preparation is (1) produced from the initial substance..." Also, examples 1-6 in the specification refer to the same initial substance from which both the active medicinal substance in a therapeutic dose and the potentiated form are made).

Applicant also refers the attention of the Patent Office to the fact that the term "chemically homogeneous" in reference to the active medicinal substance and the potentiated form in the previous version of Claim 17 and in the specification is the result of an imprecise translation of the original Russian-language application into English. In particular, in the original specification it has been written several times that the active substance (which is also the carrier, as claimed in dependent Claim 19) has a chemical formula, and that the referenced chemical formula is the same for *the initial substance*. That initial substance is used to prepare the active medicinal substance in a therapeutic dose (Claim 17) and the same initial substance is used to prepare the potentiated medicinal preparation by the homeopathic technology (Claim 17). The original specification does not say that the resulting products (active medicinal substance and the potentiated preparation) have the identical resulting chemical formula, the specification consistently says that only the same initial substance is used for making two different forms (active and potentiated) that are then combined in the bipathic medication. The amendments to the relevant paragraphs of the specification, correcting the imprecise translation of the original specification, are presented in this response. The undersigned attorney attests that she is fluent in both Russian and English languages, including the technical language, and that the presented corrections to the English specification are true and correct.

What follows from the above-presented explanation and clarification is that the *resulting* chemical structure of the active form and the potentiated form are not the same, contrary to the understanding of the Patent Office as reflected in the Office Action. Applicant has already written in page 10 of the response dated February 7, 2008, that:

> "Homeopathy asserts that this process can maintain a substance's healing properties regardless of how many times it has been diluted. **Many homeopathic remedies are so highly diluted that not one molecule of the original substance remains in the homeopathic dilution. Potentiated diluted remedy is believed (without being committed to any specific scientific theory) to have modified the properties of the solvent molecules or the clusters of the solvent molecules to cause therapeutic effect**.

> While no definite scientific theory exists to explain how potentiated homeopathic remedies work, it has been shown that they work." (emphasis added)

It has been known that potentiated remedies do change or modify the properties of the molecules of the solvent in which the ultra-dilution happens. So the potentiated preparation (or potentiated form) is not simply a highly diluted initial substance with an identical chemical formula, as argued by the Patent Office, but essentially a modified solvent. There is nothing in the amended Claim17 that asserts that the modified solvent in the form of a potentiated preparation has the same chemical structure as the initial substance in homeopathic solutions. While, as presented above, there is no definite scientific theory that explains that phenomenon, the definite scientific explanation or theory is not required for patentability of the present invention, because it has been long established that

> "[I]t is not a requirement of patentability that an inventor correctly set forth, or even know, how or why the invention works." *Newman v. Quigg* , 877 F.2d 1575, 1581, 11 USPQ2d 1340, 1345 (Fed. Cir. 1989); see also *Fromson v. Advance Offset Plate, Inc.*, 720 F.2d 1565, 1570, 219 USPQ 1137, 1140 (Fed. Cir. 1983) ("[I]t is axiomatic that an inventor need not comprehend the scientific principles on which the practical effectiveness of his invention rests."). Furthermore, statements that a physiological phenomenon was observed are not inherently suspect simply because the underlying basis for the observation cannot be predicted or explained." *In re Cortright*, 165 F.3d 1353, 1359, 49 USPQ2d 1464 (Fed. Cir. 1999).

It is important to emphasize, as it has been claimed before and is worded more specifically in the presently amended Claim 17, that the active medicinal substance and the potentiated form (modified solvent) differ in how they act on an organism (described in the last paragraph on Page 3 of the specification). In general, as claimed in amended Claim 17 and described all throughout the specification, it is the combining of the active medicinal substance and the potentiated form that leads to an increase in the therapeutic efficiency of the medicinal substance, as compared to that of the active medicinal substance alone. This is the effect of the bipathic medication discovered by Applicant that

is not disclosed, taught or hinted to anywhere in the Jonsson patent cited by the Patent Office.

For example, enclosed with this response are two articles that publish the results of the experiments conducted earlier by Applicant (similarly to what is described in Examples 1-6 in the Specification). The experiments described in the enclosed articles show the difference in the therapeutic effect between a combination of active medicinal substance made of the initial substance and the potentiated form of the same initial substance (the bipathic medication) as compared with a non-bipathic combination of the medicinal form with distilled water. The examples of such medicinal substances in the two articles are morphine and phenazepam. The increased therapeutic effect is clearly shown for the bipathic medications described in the articles.

Therefore, as follows from the arguments and reasons provided above, each and every element of amended independent Claim 17 is not disclosed in the cited Jonsson patent, so amended Claim 17 is patentable in view of the requirements of 35 U.S.C. 102(b) or, in the alternative, 35 U.S.C. 103(a).

The same arguments and reasons as presented above support Applicant's assertion that independent amended Claims 23 and 35 are patentable over the Jonsson patent in view of the requirements of 35 U.S.C. 102(b) or, in the alternative, 35 U.S.C. 103(a).

For the same reason Claims dependent off independent Claims 17, 23 and 35 are patentable over the Jonsson patent.

Claim 29 was rejected under 35 U.S.C. 102(b) or, in the alternative, under 35 U.S.C. 103(a) over Cohen *et al.* (US Patent No. 3,901,967). This rejection is respectfully traversed for the same reasons as presented above.

Claim 30 was rejected under 35 U.S.C. 102(b) or, in the alternative, under 35 U.S.C. 103(a) over Sirany (US Patent No. 4,987,127). This rejection is respectfully traversed for the same reasons as presented above.

Claim 31 was rejected under 35 U.S.C. 102(b) or, in the alternative, under 35 U.S.C. 103(a) over Nobile (US Patent No. 3,134,718). This rejection is respectfully traversed for the same reasons as presented above.

Claim 32 was rejected under 35 U.S.C. 102(b) or, in the alternative, under 35 U.S.C. 103(a) over Massey *et al.* (US Patent No. 4,839,341). This rejection is respectfully traversed for the same reasons as presented above.

Claim 33 was rejected under 35 U.S.C. 102(b) or, in the alternative, under 35 U.S.C. 103(a) over Jonsson *et al.* (US Patent No. 4,292,324). This rejection is respectfully traversed for the same reasons as presented above.

Claim 34 was rejected under 35 U.S.C. 102(b) or, in the alternative, under 35 U.S.C. 103(a) over Albert Stock John *et al.* (US Patent No. 3,032,584). This rejection is respectfully traversed for the same reasons as presented above.

It is believed that the present application is in condition for allowance. A Notice of Allowance is respectfully solicited. Should any questions arise, the Examiner is encouraged to contact the undersigned.

Respectfully submitted,

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